K012351

SEP 1 8 2001

510(k) SUMMARY

SUBMITTED BY: BECTON, DICKINSON AND COMPANY
7 LOVETON CIRCLE
SPARKS, MD 21152

CONTACT: Colleen Rohrbeck, Regulatory Affairs Specialist

TELEPHONE: (410) 316-4988

PREPARED: July 24, 2001

DEVICE NAME: BDProbeTec™ ET *Chlamydia trachomatis* and *Neisseria gonorrhoeae* Amplified DNA Assays

PREDICATE DEVICES: *Neisseria gonorrhoeae* culture
Abbott LCx® *Neisseria gonorrhoeae* Assay

INTENDED USE: The BDProbeTec™ ET *Chlamydia trachomatis* and *Neisseria gonorrhoeae* Amplified DNA Assays, when tested with the BDProbeTec™ ET System, use Strand Displacement Amplification (SDA) technology for the direct, qualitative detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* DNA in endocervical swabs, male urethral swabs, and in female and male urine specimens as evidence of infection with *C. trachomatis*, *N. gonorrhoeae*, or of co-infection with *C. trachomatis* and *N. gonorrhoeae*. Specimens may be from symptomatic or asymptomatic males and females. A separate Amplification Control is an option for inhibition testing (BDProbeTec™ ET CT/GC/AC Reagent Pack).

DEVICE DESCRIPTION:

The BDProbeTec™ ET *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (GC) amplified DNA assays utilize homogeneous SDA technology as the amplification method and fluorescent energy transfer (ET) as the detection method to test for the presence of CT and GC in clinical specimens.

For each assay, the SDA reagents are dried in two separate microwell strips. First, the processed sample is added to the Priming Microwell which contains the amplification primers, fluorescent labeled detector probe, and other reagents necessary for amplification. However, because no enzymes are

present in the priming microwell strips, no amplification occurs at this step. After incubation, the reaction mixture is transferred to the Amplification Microwell, which contains two enzymes (a DNA polymerase and a restriction endonuclease) necessary for SDA. It is in this latter microwell in which amplification and detection occurs. The Amplification Microwells are sealed to prevent contamination and then incubated in a thermally controlled fluorescent reader which monitors each test well for the generation of amplified products. The presence or absence of CT and GC is determined by relating the BDProbeTec™ ET MOTA (Method Other Than Acceleration) scores for the sample to pre-determined cutoff values. The MOTA score is a metric used to assess the magnitude of signal generated as a result of the reaction.

If the CT/GC Reagent Pack is used, each sample and control are tested in two discrete microwells: *C. trachomatis* and *N. gonorrhoeae*. Results are reported through an algorithm as positive or negative. If the CT/GC/AC Reagent Pack is used, each sample and control are tested in three discrete microwells: *C. trachomatis, N. gonorrhoeae,* and the Amplification Control. The purpose of the Amplification Control is to identify a sample that may inhibit the SDA reaction. Results are reported through an algorithm as positive, negative, or indeterminate.

DEVICE COMPARISON:

The BDProbeTec™ ET GC assay is similar to culture methods in that:

- Both assays detect *N. gonorrhoeae*
- Both assays detect *N. gonorrhoeae* in endocervical and urethral swabs and male and female urine specimens

The BDProbeTec™ ET GC assay differs from culture methods in that:

- The BDProbeTec™ ET GC assay detects DNA of the *N. gonorrhoeae* organism while culture methods detect the whole living organism
- The BDProbeTec™ ET GC assay can provide results in one hour while culture methods can take up to 72 hours

The BDProbeTec™ ET GC assay is similar to the Abbott LCx® *N. gonorrhoeae* assay in that:

- Both assays utilize nucleic acid amplification technology
- Both assays have the same intended use
- Both assays detect *N. gonorrhoeae* from endocervical and urethral swabs and male and female urine specimens
- Both assays can test specimens from symptomatic and asymptomatic patients
- Both assays are qualitative

The BDProbeTec™ ET GC assay differs from the Abbott LCx® *N. gonorrhoeae* assay in that:

- The BDProbeTec™ ET GC assay uses SDA technology while LCR technology is used for the Abbott LCx® *N. gonorrhoeae* assay
- The BDProbeTec™ ET GC assay uses simultaneous amplification/detection while the Abbott LCx® *N. gonorrhoeae* assay uses amplification followed by detection
- The BDProbeTec™ ET GC assay can be performed in one room while the Abbott LCx® *N. gonorrhoeae* assay requires separate sample processing and amplification/detection areas (i.e. unidirectional workflow)
- The BDProbeTec™ ET GC assay utilizes a dried reagent format while the Abbott LCx® *N. gonorrhoeae* assay utilizes liquid reagents
- The BDProbeTec™ ET GC assay has an amplification control to monitor for inhibition while the Abbott LCx® *N. gonorrhoeae* assay does not have an amplification control

SUMMARY OF PERFORMANCE DATA:

CLINICAL STUDIES:

Performance characteristics for the BDProbeTec™ ET CT and GC Amplified DNA Assays were initially established in a multicenter study at seven geographically diverse clinical sites. The final data analysis included 4108 CT and 4105 GC specimens collected from 2109 patients attending sexually transmitted disease clinics, OB/GYN clinics, family planning clinics, adolescent clinics, and emergency rooms. In this study, the seven sites collected 183 and 184 asymptomatic male GC swab and urine specimens, respectively.

To supplement the asymptomatic male GC data, a similar study was conducted at three clinical sites; one of which participated in the original evaluation. The study included collecting asymptomatic male urethral swab and urine specimens. A total of 987 specimens collected from 519 patients were used in the data analysis. Results were pooled with the specimens collected in the original study.

BDProbeTec™ ET *N. gonorrohoeae* results were compared to culture and patient infected status (for this study, patient infected status was defined as a patient with a positive GC culture). Sensitivity for asymptomatic male urethral swabs and male urines was 95.5% and 100%, respectively. Specificity for asymptomatic male urethral swabs and male urines was 99.4% and 99.5%, respectively.

The BDProbeTec™ ET *Neisseria gonorrhoeae* results in an asymptomatic male population are substantially equivalent[1] to GC culture methods that were in use prior to May 28, 1976 and to the Abbott LCx ® *Neisseria gonorrhoeae* Assay.

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[1] The term "substantial equivalence" as used in this 510(k) notification is limited to the definition of substantial equivalence as found in the Federal Food, Drug and Cosmetic Act, as amended and as applied under 21 CFR 807, Subpart E under which a device can be marketed without pre-market approval or reclassification. A determination of substantial equivalency under this notification is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matters. No statements related to, or in support of substantial equivalence herein shall be construed as an admission against interest under the US Patent Laws or their application by the courts.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 1 8 2001

Ms. Colleen Rohrbeck
Regulatory Affairs Specialist
Becton, Dickinson and Company
7 Loveton Circle
Sparks, MD 21152

Re: K012351
Trade/Device Name: BDProbeTec™ ET *Chlamydia trachomatis* and *Neisseria gonorrhoeae* Amplified DNA Assays
Regulation Number: 21 CFR 866.3390, 866.3120
Regulation Name: Neisseria spp. Direct serological test reagents, Chlamydia serological reagents.
Regulatory Class: II
Product Code: LSL, MKZ
Dated: July 24, 2001
Received: July 25, 2001

Dear Ms. Rohrbeck:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K012351

Device Name: BDProbeTec™ ET *Chlamydia trachomatis* and *Neisseria gonorrhoeae* Amplified DNA Assays

Indications for Use:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K012351

(Optional Format 3-10-98)